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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,387	03/14/2001	Kaia Palm	CEMRES.001 A	3322
20995	7590	01/29/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/808,387

Applicant(s)

PALM ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2, 11-20 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 11-27-01
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-41-02  
7-24-03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### *Status of the claims*

Claims 1-30 are pending.

Applicants' request for extension of time of one month (filed 17 November 2003) has been entered.

#### *Election/Restrictions*

Applicant's election (filed 17 November 2003) without traverse of Group I, claims 1-10 and 21-29 is acknowledged. Also, in the response filed 17 November 2003, applicants further elect nucleotide sequence SEQ ID NO:21 for examination. Note that claim 2 is drawn to non-elected nucleotide sequence SEQ ID NO:48. Thus, claim 2 and claims 11-20 and 30 of Group II are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Thus, claims 1, 3-10 and 21-29 will be examined insofar as to the elected patentably distinct polynucleotide of Group I, SEQ ID NO:21.

#### **IDS**

The references listed in Information Disclosure statements filed 27 November 2001, 11 February 2002 and 24 January 2003 have been received and considered.

#### *Specification/Claim Objections*

The disclosure is objected to because of the following informalities:

(1) In page 2, line 3, "CNS" and "PNS" should be spelled out in full at the first instance of use. See also page 6, line 6, "NGF", "BDNF", "NFL-L", "GAP-3" and "NHRs" and line 26, "NLS"; and page 51, line 15, "2-ME".

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(2) In page 15, line 29, "SEQ. ID. NOs." should be changed to "SEQ ID NO:"; the same changes should be made throughout the specification.

In claim 1, "Neu" should be spelled out for the first instance of recitation in the claims.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, the second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-10 and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "C3HC4 RING-zinc finger domain"; the recitation is not apparent as to whether or not "C3HC4" refers to a name of said domain or description of structural feature of said finger domain, e.g., Cys(3--His(1)--Cys(4). The dependent claims are also rejected.

Claim 3 recites the limitation "the nucleic acid". There is insufficient antecedent basis for this limitation in claim 1 from which claim 2 depends. See also claims 4-5.

Claim 7 is indefinite as to the recitation "capable of" since it does not equate to indication of the specific hybridization must actually occur (see "... which hybridizes under stringent condition..." at page 27 instead). The dependent claims are also rejected.

Claim 8 is unclear as to "at about room temperature" because the room temperature per se does not define a standard temperature rather varies from location to location where the hybridization is performed.

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Claim 24 recites “a protein encoded by said nucleotide sequence”; the recitation is unclear as to whether or not “a protein” refers to any protein other than Neu protein or a chimera (fusion) protein comprising Neu protein. The dependent claims are also rejected.

Claim 25 is indefinite because the recitation “the Neu polypeptide encoding nucleotide sequence” is unclear; how does the polypeptide encode the nucleotide sequence? See also claims 27-29. The dependent claims are also rejected. Also, Claim 25 recites the limitation “the Neu polypeptide”. There is insufficient antecedent basis for this limitation in claim 24 from which claim 25 depends.

### ***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura, H. *et al.* (*Oncogene* (1998) 16, 1009-1019).

Nakamura et al. teach an isolated cDNA (1.8 Kb) (see page 1011 and Figure 6) that encodes a Neu polypeptide and C<sub>3</sub>HC<sub>4</sub>-type RING zinc-finger domain (see page 1011, the right column, and Figure 7), as applied to the claim 1 of the current application.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Price, B. D. *et al.* (*EMBO J.* (1993) 12, 2411-2418).

Price et al. teach an isolated cDNA encoding Neu polypeptide that comprises a C<sub>3</sub>HC<sub>4</sub>-type RING zinc-finger domain (see abstract, page 2412, and Figures 1-3), wherein the Neu polypeptide acts as a transcriptional factor (regulator). The Price et al. teaching meets the limitation set forth in the claim 1 of the instant application.

Claims 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischmann, R. D. et al. (US Pat. NO. 6294328).

Fleischmann et al. teach a polynucleotide sequence which hybridizes under the conditions set forth in claims 8-10 to the SEQ ID NO:21 of the instant application. See Fleischmann's sequence (nucleotides 1217502 to 1218624) which is complementary (by 43.9% sequence identity) to the SEQ ID NO:21 segment (nucleotides 423-1545). Thus, Fleischmann et al. anticipate claims 7-10 of the current application.

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Claims 1, 21-24, 27 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Yeh, E. *et al.* (*EMBO J.* (2000) 19, 4827-2837).

Yeh et al. teach an isolated polynucleotide encoding a Neu polypeptide that comprises a C<sub>3</sub>HC<sub>4</sub>-type RING zinc-finger domain (see abstract, page 4828, the left column), as applied to the application claim 1.

Yeh et al. teach an expression vector comprising the above-mentioned polynucleotide, i.e., *neu* gene which is cloned in an expression vector termed pUAST (see the bridging pages 4832-4833), as applied to claims 21-22 of the current application.

Yeh et al. teach a host cell (e.g., an embryo cell) comprising the above-mentioned vector (see "Methods and Materials" section, pages 4834-4835, and Figure 9), as applied to claim 23 of the instant application.

Also, Yeh et al. teach a method of making the Neu polypeptide comprising inserting the isolated *neu* gene into the expression vector, pUAST, and introducing the vector into host cells via P-element-mediated transformation (see page 4835, the right column, the first paragraph, Figure 7, and pages 4832-4833). The Yeh et al. teaching thus anticipates the application claims 24, 27 and 29.

Claims 24 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Guy, C. T. *et al.* (*J. Biol. Chem.* (1996) 271, 7673-7678).

Guy et al. teach a method of making the Neu polypeptide comprising inserting the isolated polynucleotide comprising *neu* gene into the expression vector, pMMTV-NT (see Figure

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1, "Materials and Methods" section), and introducing said vector into host cells (mammary gland cell) *via* microinjection (see page 7674). The Yeh et al. teaching meets the limitation set forth in the application claim 24, 27 and 29.

Also, Guy et al. teach isolating and characterizing the produced polypeptide comprising Neu polypeptide thereof through Western analyses (see Figure 3), as applied to claim 24 of the instant application.

Thus, Guy et al. reference anticipates claims 24 and 26-29 of the current application.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571 272-0949.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

*SWL*

Samuel Wei Liu, Ph.D.

January 21, 2004

*Karen Cochrane Carlson Ph.D.*

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER